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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,898	04/15/2004	William J. Boyle	A-451N	8965
21069 AMGEN INC. MAIL STOP 28-2-C ONE AMGEN CENTER DRIVE THOUSAND OAKS, CA 91320-1799	7590 09/17/2009			
			EXAMINER	
			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			09/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,898

Applicant(s)

BOYLE, WILLIAM J.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-68 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 58-68 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date 9/3/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/3/09 has been entered.

2. Claims 58-68 are under consideration.

3. The abstract of the disclosure is objected to because it does not disclose the claimed invention (aka the method of claim 58). Correction is required. See MPEP § 608.01(b).

4. Applicant is required to update the status of all US applications disclosed in the instant application.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 58-62,64-68 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

There is no support in the specification as originally filed for the methods of claims 58-62,64-68. The claims encompass use of in vivo assays and unspecified assays wherein original claim 43 is limited to an in vitro method. Regarding the specification, page 23, the cited passage is limited to an in vitro method wherein OPGb/ligand binding is measured. Said passage also includes an additional step wherein the compound is measure for agonist or antagonist activity, but there is no

description as to how said activity is measured. Regarding claim 62, original claim 43 is limited to a method wherein osteoclast formation is measured in a cell culture. There is no written description of the scope of the claimed inventions in the specification as originally filed (aka the claimed inventions constitute new matter).

Regarding applicants comments about the specification, page 30, the cited passage discloses that: "Compounds which increase or decrease the interaction of OPG binding protein with ODAR may also be evaluated for in vivo activity by administration of the compounds to mice followed by measurements of bone density using bone scanning densitometry or radiography.". Thus, said passage is limited to a description of compounds which decrease the interaction of OPG binding protein and ODAR, wherein the claims under consideration are not so limited. The claims encompass compounds which decrease the functional activity of OPG binding protein recited in the claims by means other than decreasing the interaction between said protein and ODAR wherein the specification as originally filed does not provide support for said invention. In addition said passage also includes further limitations (evaluated for in vivo activity by administration of the compounds to mice followed by measurements of bone density using bone scanning densitometry or radiography) wherein the absence of said limitation broadens the scope of the claimed invention such that it encompasses methods of in vivo evaluation other than those disclosed in the specification. Regarding Example 15, said example is limited to use of ODAR-Fc in mice for the purpose of establishing the activity in vivo in a specific mouse model disclosed in said example. Said example doesn't disclose use of molecules other than ODAR-Fc and does not even disclose that said molecule has an effect on OBP binding protein. It also does not disclose the scope of the claimed invention which encompasses in vivo assays other than the specific method used in said example. Original claim 29 in US 09/052,521 is not drawn to the claimed invention. Said claim does not contain the additional method steps of claim 58, lines 4-6. Said method merely refers to an assay for measuring bind of a compound to OBP binding protein wherein binding of the compound is measured.

7. Claim 60 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed method.

The claimed method encompasses use of human ODAR protein. The only human ODAR protein disclosed in the specification is RANK with the sequence as per specified in the cited reference. The claims encompass use of human ODAR variants, mutants and alleles, yet there is no disclosure of such specific proteins in the specification and their identity is unpredictable. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of

The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, the claimed method encompasses use of human ODAR protein. The only human ODAR protein disclosed in the specification is RANK with the sequence as per specified in the cited reference referred to in the specification. The claims encompass use of human ODAR variants, mutants and alleles, yet there is no disclosure of such specific proteins in the specification and their identity is unpredictable. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein.

8. Regarding the application of prior art, for the same reasons that claims lack written description as per the reason stated above, they are not entitled to priority to the parent applications for which priority is claimed. Regarding claim 63, there is no support for said claim (or cancelled claim 43) in the parent applications to which priority is claimed. Claim 43 which provides support for claim 63 was filed with the instant application and therefore does not constitute new matter. However, there is no disclosure of said method in the parent applications to which priority is claimed. Regarding the specification, page 23, the cited passage is limited to an in vitro method

wherein OPGbp/ligand binding is measured. Said passage also includes an additional step wherein the compound is measure for agonist or antagonist activity, but there is no description as to how said activity is measured.

9. Applicant states that this application is a continuation or divisional application of the prior-filed application. A continuation or divisional application cannot include new matter. Applicant is required to change the relationship (continuation or divisional application) to continuation-in-part because this application contains the following matter not disclosed in the prior-filed application. The new matter not supported in the specification is that referred to in paragraphs 6 and 9 of this Office Action.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 58-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle (US Patent 6,316,408) in view of Choi et al. (WO 02/16551). Applicants arguments have been considered and deemed not persuasive.

Boyle teaches OPGbp of SEQ. ID. No. 4 and the various fragments recited in the claims (see columns 7-9). Boyle teaches that compounds that interact with OPGbp can be screened by measuring the binding of said compound to OPGbp and then further characterizing the ability of said compound to decrease OPGbp activity (see column 11, third paragraph). Boyle teach that such compounds can include antibodies (see column 9, penultimate paragraph). Boyle teaches that OPGbp binds to ODAR (see columns 12-15). Boyle et al. do not teach the method of claim 58 using osteoclast formation in vitro or the method of claim 64. Choi et al. disclose in vitro assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said protein (see pages 18-20). Choi et al. also teach that said compounds can also be evaluated in vivo wherein the effect on the test cell is evaluated in vivo (see page 21, second paragraph). Boyle disclose that OPGbp effects osteoclast

activity and bone resorption (see column 2, penultimate paragraph). Decreased bone resorption results in increased bone density. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Boyle teaches that compounds that interact with OPGbp can be screened by measuring the binding of said compound to OPGbp and then further characterizing the ability of said compound to decrease OPGbp activity whilst Choi et al. disclose that in vitro and in vivo assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said compound. One of ordinary skill in the art would have been motivated to do the aforementioned because Choi et al. disclose that in vitro and in vivo assays using a cell responsive to a particular protein can be used to screen for compounds which inhibit the activity of said compound.

Applicants arguments regarding priority are addressed above.

12. No claim is allowed.

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644